

# EXHIBIT H

IN THE UNITED STATES DISTRICT COURT  
DISTRICT OF MINNESOTA

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IN THE MATTER OF	)	
	)	
IN RE BAIR HUGGER FORCED AIR	)	
WARMING	)	
PRODUCTS LIABILITY LITIGATION	)	
	)	
Plaintiff,	)	
	)	PRETRIAL ORDER NO: 7
v.	)	Protective Order
	)	MDL No. 15-2666
3M COMPANY AND ARIZANT	)	(JNE/FLN)
HEALTHCARE INC.	)	
Defendant.	)	

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DEPOSITION OF PAUL MCGOVERN

VOLUME II

Thursday, January 5, 2017

AT: FAEGRE BAKER DANIELS LLP

Taken at:

7 Pilgrim Street

London EC4V 6LB

United Kingdom

Court Reporter:

Louise Pepper: Accredited Real-time Reporter

Videographer: Simon Addinsell

JOB NO. 117121

1  
2  
3 **A P P E A R A N C E S**

4 Appearing for the Plaintiff:

5 **MR. MICHAEL SACCHET**  
6 **CIRESI CONLIN**  
7 **225 South 6th Street**  
8 **Minneapolis, MN 55402**

9 **GENEVIEVE ZIMMERMAN**  
10 **MESHBESHER & SPENCE**  
11 **1616 Park Avenue**  
12 **Minneapolis, MN 55404**

13 Appearing for the Defendant:

14 **MR. COREY GORDON**  
15 **BLACKWELL BURKE**  
16 **431 South Seventh Street**  
17 **Minneapolis, MN 55415**

18 **MS. KATHERINE NEWMAN**  
19 **FAEGRE BAKER DANIELS**  
20 **7 Pilgrim Street, London EC4V 6LB**

21 Appearing for the Witness:

22 **MR. ANDREW HEAD**  
23 **MR. BRYAN SHACKLADY**  
24 **FORSTERS**  
25 **31 Hill Street**  
**London W1J 5LS**

1  
2 **W I T N E S S I N D E X**

3 Examination by MR. SACCHET .....239

4 Examination by MR. C. GORDON .....459

5 **E X H I B I T I N D E X**

6 Exhibit 1 Email chain between P. ....263

7 McGovern and M. Albrecht,

8 Bates stamped Albrecht\_0016487

9 Exhibit 2 Email chain between Mark .....287

10 Albrecht, Paul McGovern, Mike

11 Reed and others, dated 30 June

12 to 3 July, 2010

13 Exhibit 3 Forced Air Warming .....289

14 Demonstration DVD

15 Exhibit 4 CDC document entitled .....298

16 "Healthcare Infection Control

17 Practices Advisory Committee

18 Record of the Proceedings",

19 dated November 5-6, 2015,

20 previously marked as Exhibit

21 208, Bates stamped

22 3MBH01344612-01344685

23 Exhibit 5 Document entitled .....306

24 "Forced Air Warming (FAW) and

25 Surgical Site Contamination

First Draft" dated 27/9/09

Exhibit 6 Document entitled "Do .....308

Forced Air Warming Devices

Increase Bacterial

Contamination of Operative

Field? - Simulated

experimental analysis".

Exhibit 7 Email chain dated 8-11 .....309

November, 2009, subject line:

"FAW"

Exhibit 8 Document Bates stamped .....316

3MBH00107863-00107870

1  
2 Exhibit 9 Document entitled "Do .....324

3 Forced Air Warming Devices

4 Increase Bacterial

5 Contamination of Operative

6 Field? - Simulated experiment

7 analysis".

8 Exhibit 10 Email chain between .....336

9 Paul McGovern and Val

10 Edwards-Jones"Re Saturday",

11 dated 26 November - 20

12 December 2009

13 Exhibit 11 Email chain between .....337

14 Paul McGovern, David Leaper,

15 Andrew Sprowson and Thomas

16 Symes, "Prof David Leaper

17 Visit", dated 10 September - 2

18 December 2009

19 Exhibit 12 Email chain between .....342

20 Paul McGovern and Mike Reed,

21 dated 21 February 2010,

22 "Laminar flow tests".

23 Exhibit 13 Article co-published by .....347

24 Paul McGovern and others,

25 entitled "Forced-air warming

and ultra-clean ventilation do

not mix." Bates stamped

Belani\_000190-000197

Exhibit 14 Article entitled .....353

"Patient Warming Excess Heat:

The Effects on Orthopedic

Operating Room Ventilatio

Performance", Bates stamped

Belani\_000040-000045

Exhibit 15 Email chain between .....359

Mark Albrecht, Paul McGovern

and others, dated 1 February

2011, "Manuscript with updated

joint infection data covering

an additional 200 or so".

Exhibit 16 Excel spreadsheet with .....365

data analysis

1  
2 Exhibit 17 Email chain between .....372

3 Mark Albrecht, Mike Reed, Paul

4 McGovern and others, dated 18

5 February - 1 March 2011,

6 "Signatures on Transmittal

7 Letter".

8 Exhibit 18 Email chain between .....373

9 Paul McGovern and Mark

10 Albrecht, dated 19 May - 23

11 May, 2011, "Fwd: JBJS [BR] log

12 No. 27124 - Invitation to

13 resubmit

14 Exhibit 19 Email chain "Re .....382

15 McGovern" between Robin

16 Humble, Scott Augustine, Paul

17 McGovern and others plus

18 attachment entitled "Observed

19 reduction in periprosthetic

20 joint infections: Antibiotics

21 or warming technique?", dated

22 25 March - 17 June 2016.

23 Exhibit 20 Journal of Bone and .....391

24 Joint Surgery document

25 entitled "Wound Complications

Following Rivaroxaban

Administration".

Exhibit 21 Paper entitled "Return .....396

to theatre following total hip

and knee replacement, before

and after the introduction of

rivaroxaban".

Exhibit 22 Journal of .....403

Tissueviability paper entitled

"A prospective randomised

study comparing the jubilee

21 dressing method to a standard

22 adhesive dressing for total

23 hip and knee replacements",

24 authored by Neil G. Burke and

25 others.

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1 Exhibit 23 Email chain between .....410  
2 Mark Albrecht and Mike Reed,  
3 "Full workup of stats you  
4 requested", dated 29 November,  
5 2011.

6 Exhibit 24 Email from Mark .....416  
7 Albrecht to Scott Augustine,  
8 with attachment, dated  
9 11/22/2015, Bates stamped  
10 Albrecht\_0002079-0002086

11 Exhibit 25 Anesthesia & Analgesia .....445  
12 document entitled "Patient  
13 Warning Excess Heat: Effects  
14 on OR Ventilation Performance  
15 During Total Knee  
16 Replacement", Bates stamped  
17 Belani\_000002-000039

18 Exhibit 26 Email from Mark .....454  
19 Albrecht to Paul McGovern and  
20 others, "Fwd: A&A Decision for  
21 MS#: AA-D-11-01334", dated 25  
22 October 2011

23 Exhibit 27 Email chain between .....455  
24 Mark ALbrecht, Mike Reed and  
25 others, "Fwd: A&A DEcision for  
MS#: AA-D-11-01334R1", dated  
11 January 2012.

Exhibit 28 Spreadsheet, Bates .....461  
stamped  
AUGUSTINE\_0005193-0005487

Exhibit 29 Printout of spreadsheet .....463  
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Exhibit 30 Screenshots of FAW v .....500  
CWB YouTube video

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DR. PAUL MCGOVERN

## P R O C E E D I N G S

THE VIDEOGRAPHER: This is Day 2 of the deposition  
of Dr. Paul McGovern. The deposition started yesterday  
4 January, today is 5 January 2017, and it is 9:24 a.m.  
This is the beginning of DVD 1 in volume 2 of Dr. McGovern's  
deposition. Everybody who was in the room yesterday is here  
today.

Can I remind the witness he was sworn in  
yesterday and is still under oath. Can you --

THE WITNESS: Yes.

THE VIDEOGRAPHER: You're on the record, counsel.

It is 25 past 9.

EXAMINATION BY MR. SACCHET:

BY MR. SACCHET:

Q. Good morning, Dr. McGovern.

A. Good morning.

Q. As I mentioned yesterday, my name is Mr. Sacchet,  
and I represent the plaintiffs 3M. Yesterday my learned  
friend on the other side reviewed some of the ground rules  
for the deposition. I'm going to go through few more today,  
just to make sure we're on the same page with respect to the  
procedures for our conversation. As you know, I'll be  
asking you questions under oath and you'll be responding to  
them. If at any time you don't understand a question or if

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DR. PAUL MCGOVERN

you don't hear the question, please let me know, okay?

A. Yes.

Q. As was mentioned yesterday, it's best for the  
record and the court reporter, if I ask a question, that you  
let me finish asking the question before you answer, and  
I'll do the same with respect to you in refraining from  
asking a question before you've finished your answer.  
Please provide audible "Yes" or "No" answers with respect to  
the questions as opposed to a nodding or shaking of the  
head. Is that agreeable?

A. Yes.

Q. And if at any time you need a break, just let me  
know, and I'll find an appropriate spot to pause.

A. Sure.

Q. Before we jump into your background, with respect  
to your educational and professional history, just a few  
preliminary items. You've never met me before, have you?

A. Not before yesterday, no.

Q. And prior to yesterday, you'd never spoken to me  
before, be it via e-mail or phone?

A. That is correct.

Q. You've never spoken to any members of the  
plaintiff's counsel in this matter, have you?

A. That is correct.

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Q. Have you ever spoken to anyone on the side of the  
defense, prior to yesterday?

A. I'd received communications from various people on  
the side of the defense. I have only communicated with them  
through my lawyers.

Q. Okay. Do you recall who those individuals were  
that attended the --

A. Stephen Llewellyn, from Faeger Baker Daniels.  
I received a LinkedIn message from a lawyer in the United  
States, but I don't remember their name.

Q. Do you recall the content of the message?

A. It was similar to the initial contact from Stephen  
Llewellyn, saying that 3M would like to depose me, and  
asking me to get back in touch to arrange that.

Q. And did you get back in touch to arrange that?

A. I did not reply to the LinkedIn message at all, and  
I replied to Stephen Llewellyn through my lawyers when  
I arranged legal representation.

Q. Okay. So other than contact via your attorney,  
you've had no personal contact with anyone on the other  
side?

A. That is correct.

Q. I know you spoke a little bit yesterday about your  
background as well, and I'm going to review some of that

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DR. PAUL MCGOVERN  
in jubilee dressing that occurred during the time in which the data was collected for the McGovern study impacted infection rates?

MR. C. GORDON: Object to the form of the question: lack of foundation, incomplete hypothetical.

A. It's not possible to say, in my opinion. The numbers in this study are too small. You have a number of patients that is 124, and the numbers are too small to be able to draw a meaningful conclusion in terms of infection, with regard to these two variables, in my opinion.

BY MR. SACCHET:

Q. So if I could point out, to the extent that this would change your mind, the asterisks which are denoted in the right-hand column of the standard adhesive dressing column; do you see those?

A. Yes.

Q. And a single asterisk stands for a P value of less than 0.05; correct?

A. Mm-hm, yes.

Q. And a double asterisk stands for a P value of 0.01 and less?

A. Yes.

Q. And three asterisks stands for a P value of 0.001 or less; correct?

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A. Yes.

Q. The infection row has no such asterisk in it, does it?

A. That's correct.

Q. So, because we established earlier that statistical significance begins at 0.05, which is a single asterisk ...

A. Right.

Q. ... presumably this 0 percent infection rate, the difference between 0 and 0 is non-significant; correct?

A. No, that's not how I would interpret this. There is no data to draw a meaningful conclusion from. You need to have some data, by my understanding, to be able to draw a conclusion of statistical significance. You can't comment on whether these data are statistically significant. If one were designing this study purely to look at infection rates between the two dressings, it is likely that the study would need to include more patients and the study -- and to ensure it was sufficiently powered to be able -- "powered" meaning to have enough patients in it -- to see enough infections to be able to draw a meaningful conclusion.

The fact that there were no infections in 124 patients is not surprising, because infection rates are generally low. This is a problem of research in this area. Because infection is rare, thankfully, you need

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large numbers of patients in studies to see if one intervention has a difference with another intervention, in terms of infection rates. In my opinion, this study does not demonstrate superiority of one adhesive dressing over another, purely in terms of infection.

Q. Fair enough --

A. It may for other conditions, such as blistering and leakage, but for infection -- because those are more common -- consequences post-operation, and the study appears to have been adequately powered to identify those differences and state statistical significance. But for infection, there were not enough incidences of infection to be able to draw meaningful conclusions, or a difference between the two.

Q. Are you aware of any paper that is adequately powered that shows that a change from a standard adhesive dressing to a jubilee dressing would statistically significant -- significantly alter infection rates among arthroplasties?

A. I am not aware of any such paper.

Q. Are you aware of any published papers that suggest -- I should say that find statistically significant differences between joint infection rates from the use of

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MSSA screening versus non-screening?

A. Sorry, could you say that again, please?

Q. Are you aware of any evidence that is statistically significant that suggests that the use of MSSA screening significantly impacts the rate of deep joint infections among patients?

A. I'm not aware of any such papers.

Q. Are you aware of any evidence that pre-warming, when used in combination with intraoperative warming, significantly impacts deep joint infection rates among patients?

A. I am not aware of papers which provide evidence of that.

Q. Have you seen an article by Mr. Reed and another individual, bearing the last name Refaie, which analyzed the NHS SSI bundle?

A. I presume you mean Northumbria Foundation Trust. I am aware that Mr. Reed and Mr. Refaie have done research together. I may have seen such paper but I don't remember.

Q. Do you recall Mr. Reed, in that paper, making the statement: "A switch to the alternative conductive fabric warming led to a significant decrease in deep joint infections"?

A. I -- that statement sounds familiar but I don't

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1 DR. PAUL MCGOVERN  
 2 remember reading it in a paper.  
 3 Q. Would you have any reason to doubt, if Mr. Reed  
 4 made such a statement, the accuracy of such a statement?  
 5 MR. C. GORDON: Object to the form of the  
 6 question: lack of foundation, assumes facts not in evidence.  
 7 A. If Mr. Reed indeed made that statement in a paper,  
 8 I'd have no reason to doubt the veracity of that statement.  
 9 BY MR. SACCHET:  
 10 Q. Are you aware of the fact that after the McGovern  
 11 paper was published in the Journal of Bone and Joint  
 12 Surgery, that additional data supported an elevated  
 13 odds-risk ratio?  
 14 MR. C. GORDON: Object to the form of the  
 15 question: assumes facts not in evidence, incomplete  
 16 hypothetical.  
 17 A. I was not.  
 18 BY MR. SACCHET:  
 19 Q. Okay.  
 20 (Exhibit 23 marked for identification)  
 21 Q. That's an e-mail entitled "Full workup of the stats  
 22 you requested"; correct?  
 23 A. Yes.  
 24 Q. And there is an e-mail from Mr. Albrecht to  
 25 Mr. Reed, and you are cc'd on the e-mail on November 29,

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1 DR. PAUL MCGOVERN  
 2 2011; correct?  
 3 A. Yes.  
 4 Q. And there is an attachment called "Results";  
 5 correct?  
 6 A. Yes.  
 7 Q. And if you turn the page, there is a table. Does  
 8 this table resemble the table in the published McGovern  
 9 study?  
 10 A. It does resemble it. I'll check if it is the same.  
 11 Q. There are different data points, but just in terms  
 12 of the style and form of the table?  
 13 A. Err ...  
 14 Q. It is exhibit 13, to make sure you're on the right  
 15 one.  
 16 A. I'm there. I'm on exhibit 13. Which table are you  
 17 referring to? Table 1 in exhibit 13?  
 18 Q. I am looking at -- yes. No.  
 19 A. Table 2.  
 20 Q. Yeah, the lower half of Table 2. I mean with parts  
 21 of the lower half, as well.  
 22 A. Yes, I would agree this is similar in form to part  
 23 of Table 2 in what you refer as to the "McGovern paper".  
 24 Q. Okay. And if we look at that table in the e-mail  
 25 thread, for a conductive fabric, number developing

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1 DR. PAUL MCGOVERN  
 2 infection, 7; correct?  
 3 A. Oh, yes.  
 4 Q. Number not developing infection, 792; correct?  
 5 A. Yes.  
 6 Q. For a total population of 709 patients who received  
 7 conductive fabric warming; correct?  
 8 A. Yes.  
 9 Q. That number is significantly larger than the total  
 10 population of individuals who received conductive fabric  
 11 warming in the final published paper, exhibit 13; correct?  
 12 A. That number is larger. To say it was significantly  
 13 larger would require a statistically significant test. So  
 14 be careful about using the words "statistically  
 15 significantly", but it is a larger number.  
 16 Q. How about double?  
 17 A. Let's see. Conductive fabric 792 versus 368. Yes,  
 18 I think that's a reasonable thing to say.  
 19 Q. Okay. And if we go back to the text of the e-mail,  
 20 Mr. Reed writes back to Mr. Albrecht and copies you in and  
 21 says, in the last line of the first paragraph:  
 22 "You are 3.6 times more likely to get an  
 23 infection on FAW than CFW."  
 24 Do you see that?  
 25 A. Yes. It phrases a question, but yes.

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1 DR. PAUL MCGOVERN  
 2 Q. Yes. Do you have any reason to doubt Mr. Reed's  
 3 statement to that effect?  
 4 A. It appears that Mr. Reed is asking if that is what  
 5 the data is showing in this table.  
 6 Q. And do you see, in the table itself, a demarcation  
 7 of 3.6 on the right-hand side of the odds ratio?  
 8 A. I do.  
 9 Q. So in fact Mr. Reed was referring to this table;  
 10 correct?  
 11 A. That is -- seems likely.  
 12 Q. And this table was sent as a results attachment  
 13 from Mr. Albrecht?  
 14 A. Yes.  
 15 Q. You have no reason to doubt Mr. Albrecht's ability  
 16 to conduct statistical analysis of data, do you?  
 17 A. None whatsoever.  
 18 Q. You have no reason to doubt that, based on this  
 19 patient population of those who received conductive fabric  
 20 warming, which is double the size of the patient population  
 21 in the McGovern study, that there was a 3.6 odds ratio?  
 22 A. That is what this data appears -- (overspeaking) --  
 23 MR. C. GORDON: Object to the form of the  
 24 question.  
 25 THE COURT REPORTER: Sorry, can you repeat the

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1 DR. PAUL MCGOVERN  
 2 objection, please.  
 3 MR. C. GORDON: Form.  
 4 A. That is what this data appears to show.  
 5 BY MR. SACCHET:  
 6 Q. So this data shows there is a 3.6 times increase in  
 7 infection as a result of using forced-air warming devices  
 8 compared to conductive fabric warming devices; correct?  
 9 A. That is what --  
 10 MR. C. GORDON: Object to the form of the  
 11 question.  
 12 A. That is what this table appears to show.  
 13 BY MR. SACCHET:  
 14 Q. And both this odds ratio and the odds ratio  
 15 presented in the final published McGovern study are both  
 16 above 3.0; correct?  
 17 A. Yes.  
 18 Q. So, based on this data in the increased patient  
 19 population of those who received conductive fabric warming,  
 20 this data corroborates the fact that there is at least  
 21 a three times more likely chance that patients who received  
 22 forced-air warming developed an infection, compared to those  
 23 who received conductive fabric warming?  
 24 MR. C. GORDON: Object to the form of the  
 25 question.

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1 DR. PAUL MCGOVERN  
 2 (Break taken.)  
 3 (3:04 p.m.)  
 4 THE VIDEOGRAPHER: Back on the record at four  
 5 minutes past three.  
 6 (Exhibit 24 marked for identification)  
 7 BY MR. SACCHET:  
 8 Q. Mr. McGovern, are you aware of any data that's been  
 9 collected regarding other healthcare facilities that have  
 10 shown a decreased rate of infection after the switch from  
 11 forced-air warming devices to conductive fabric warming  
 12 devices?  
 13 A. I am not.  
 14 Q. If you could take a look at the exhibit which was  
 15 just marked. The first page is an e-mail; is that correct?  
 16 A. Yes.  
 17 Q. From Mr. Albrecht to Scott Augustine, bearing the  
 18 subject line "Results" with attachments "MA\_edits"; correct?  
 19 A. Yes.  
 20 Q. And Mark Albrecht states:  
 21 "I've updated the statistics in the white  
 22 paper under \*\*MA\_edits.doc\*\*."  
 23 A. Yes.  
 24 Q. "The updates include:  
 25 "The statistics in the Table for all centers and

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1 DR. PAUL MCGOVERN  
 2 A. This data -- I can't agree with the term  
 3 "corroborates the fact". The fact is not --  
 4 BY MR. SACCHET:  
 5 Q. Also shows?  
 6 A. Yeah. Could you just repeat the phrase, please, or  
 7 rephrase that? Or --  
 8 Q. I'll rephrase the question.  
 9 Based on the data presented in this table and the  
 10 data presented in the McGovern study, both studies for  
 11 both datasets show that there was a three -- at least  
 12 a three times more likely chance that a patient  
 13 developed an infection after using forced-air warming  
 14 than conductive fabric warming?  
 15 MR. C. GORDON: Object to the form of the  
 16 question.  
 17 A. Yes. Patients who were in the group with  
 18 forced-air warming on this data appear to have had a three  
 19 times or more higher incidence of infection compared to the  
 20 conductive fabric group of patients for this study.  
 21 THE COURT REPORTER: Can I just ask you to stop  
 22 for 30 seconds, sorry.  
 23 THE VIDEOGRAPHER: Going off at two minutes past  
 24 three.  
 25 (3:02 p.m.)

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1 DR. PAUL MCGOVERN  
 2 the pooled result[s]  
 3 "The statistics in the discussion for the updated  
 4 McGovern numbers provided as provided [sic] in the  
 5 text."  
 6 Do you see that?  
 7 A. Yes.  
 8 Q. In the third paragraph it says:  
 9 "I think this is the best modeling approach  
 10 (i.e. a conservative one) for the data you have,  
 11 especially if you expect these results to be critically  
 12 questioned down the road."  
 13 Do you see that?  
 14 A. Yes.  
 15 Q. Okay. And the next page is a document entitled  
 16 "Forced-air warming link to periprosthetic total joint  
 17 replacement infections"; correct?  
 18 A. Yes.  
 19 Q. And the "Methods" says:  
 20 "To investigate whether the rising  
 21 contaminants from the waste FAW heat are linked to  
 22 PJIs, we retrospectively collected joint implant  
 23 infection data from three hospitals. We compared PJI  
 24 rates during a period of forced-air warming to PJI  
 25 rates during a period of free-air conductive fabric